

Trade Name: **PULPDENT ROOT CANAL SEALER POWDER AND LIQUID**

1.0 Commercial Product Name and Supplier	
1.1	Commercial product name / designation <b>Root Canal Sealer Powder and Liquid</b>
1.2	Application / Use Dental material for use by dental professional only.
1.2.2	SIC 851 Human health activity
1.2.3	Use Category 55
1.3	Manufacturer <b>Pulpdent Corporation</b> 80 Oakland Street P.O. Box 780 Watertown, MA 02472 USA Telephone: 1 617 926-6666 Fax: 1 617 926-6262 Email: <a href="mailto:Pulpdent@pulpdent.com">Pulpdent@pulpdent.com</a>
1.4	Emergency Telephone Number 1-800-535-5053 (24 Hour / USA)
1.5	Authorized European Representative International Business Solutions Ltd. 54 Mayfield Ridge Hatch Warren, Basingstoke, RG22 4RS UK Tel: 07989 407479 / Fax: 01256 350330 Email: <a href="mailto:s.williams5@btconnect.com">s.williams5@btconnect.com</a>
2.0 Hazards Identification	

2.1	Classification																		
2.1.1	Classification according to Regulation (EC) No 1272/2008 [CLP]	<i>Powder</i>	<table><thead><tr><th><u>Hazard Class</u></th><th><u>Hazard Category</u></th><th><u>Hazard Statement</u></th></tr></thead><tbody><tr><td>Eye irritation</td><td>2</td><td>H319</td></tr><tr><td>STOT SE</td><td>3</td><td>H335</td></tr><tr><td>Skin irritation</td><td>2</td><td>H315</td></tr></tbody></table>	<u>Hazard Class</u>	<u>Hazard Category</u>	<u>Hazard Statement</u>	Eye irritation	2	H319	STOT SE	3	H335	Skin irritation	2	H315				
<u>Hazard Class</u>	<u>Hazard Category</u>	<u>Hazard Statement</u>																	
Eye irritation	2	H319																	
STOT SE	3	H335																	
Skin irritation	2	H315																	
		<i>Liquid</i>	<table><tbody><tr><td>Eye irritation</td><td>2</td><td>H319</td></tr><tr><td>STOT SE</td><td>3</td><td>H335</td></tr><tr><td>Skin irritation</td><td>2</td><td>H315</td></tr><tr><td>Skin sensitization</td><td>1</td><td>H317</td></tr><tr><td>Respiratory sensitization</td><td>1</td><td>H334</td></tr></tbody></table>	Eye irritation	2	H319	STOT SE	3	H335	Skin irritation	2	H315	Skin sensitization	1	H317	Respiratory sensitization	1	H334	
Eye irritation	2	H319																	
STOT SE	3	H335																	
Skin irritation	2	H315																	
Skin sensitization	1	H317																	
Respiratory sensitization	1	H334																	
2.1.2	Classification according to Directive 67/548/EEC (See SECTION 16 for full text of risk phrases)		Irritant; Xi; Powder: R 36/37/38 Liquid: R 36/37/38-42/43																

2.2 GHS Label Elements  
Hazard Pictograms



Signal Word: **DANGER**

**Restricted to use by dental professional only.**

Trade Name: **PULPDENT ROOT CANAL SEALER POWDER AND LIQUID**

#### Hazard Statements

H319: Eye irritation. 2. May cause eye irritation.

H335: STOT SE. 3. May cause respiratory irritation.

H315: Skin irritation. 2. May cause skin irritation.

H317: Sensitization. 1. May cause an allergic skin reaction.

H334: Respiratory sensitization. 1. May cause allergy or asthma symptoms.

#### Precautionary Statements

P261: Avoid breathing vapor.

P280: Wear protective gloves and eye protection

P342+P311: If experiencing respiratory symptoms, call a poison center or doctor/physician.

P305+P351: If in eyes, rinse cautiously with water for several minutes.

P337+P313: If eye irritation persists, get medical advice/attention.

P302+P352: If on skin, wash with plenty of soap and water.

P333+P313: If irritation or rash occurs, get medical advice/attention.

### 3.0 Composition

**3.1** Chemical characterization of the preparation: Two-part, zinc oxide / eugenol dental cement

#### 3.2 Hazardous ingredients

	CAS Number	Name of the Ingredient	Concentration	Classification according to 67/548/EEC	Classification according to Regulation (EC) No.1278/2008 (CLP).
Powder	1314-13-2	Zinc oxide	40-60%	Irritant; Xi R 3637//38	Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315
Liquid	97-53-0	Eugenol [2-Methoxy-4-(2-propenyl) phenol]	85-95%	Irritant; Xi, R 36/37/38-42/43	Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315 Skin sensitization, 1, H317 Respiratory sensitization, 1, H334

### 4.0 First Aid Measures

- 4.1** General Information May be irritating to eyes, respiratory system and skin. Do not inhale vapors. Liquid may cause sensitization by skin contact or inhalation. Show this safety data sheet to medical personnel. Get medical attention in case of uncertainty.
- 4.2** Inhalation Move to fresh air. If necessary, administer oxygen / artificial respiration and seek medical attention.
- 4.3** Skin Contact Take off contaminated clothing. Wash skin thoroughly with soap and water for 15 minutes.
- 4.4** Eye Contact Keep eyelids apart and flush with running water for 15+ minutes. Get medical attention.

Trade Name: **PULPDENT ROOT CANAL SEALER POWDER AND LIQUID**

4.5	Ingestion	Rinse mouth with water. Do not induce vomiting. Get immediate medical attention. May be irritating to mucous membranes.
4.6	Precautions for first responders	Ventilate the area. Wear eye and skin protection.
4.7	Information for physicians	
	Symptoms	Irritation or redness in eyes, throat or on skin. Allergy or asthma symptoms
	Hazards	May be irritating to eyes, respiratory system and skin. May cause sensitization by skin contact or inhalation.
	Treatment	As above under First Aid.
<b>5.0</b>	<b>Fire Fighting Measures</b>	
5.1	Suitable extinguishing media	Foam, carbon dioxide and dry chemical. Water spray may be used to keep fire exposed containers cool.
5.2	Extinguishing media to avoid	Do not use direct water stream
5.3	Special exposure hazards in a fire	Burning liberates carbon monoxide, carbon dioxide and smoke. As with all unsaturated fats and oils, some porous materials (rags, insulation, clay) when wetted with eugenol, may undergo spontaneous combustion.
5.4	Special protective equipment for fire-fighters	A self-contained breathing apparatus should be worn by firefighting personnel. Cool exposed containers with water spray.
<b>6.0</b>	<b>Accidental Release Measures</b>	
6.1	Personal precautions.	Ventilate area. Wear gloves, lab coat and safety glasses.
6.2	Environmental precautions	Contain spilled material. Follow all government regulations.
6.3	Method for clean up	Powder: Carefully sweep into dry, covered container. Avoid raising dust. Rinse area with water.  Liquid: Absorb or wipe up spill with inert, absorbent material (paper towels or cloths). Collect for disposal in a covered container kept in a cool place. Wash area of spill with soap and water. Spills of Root Canal Liquid leave surfaces very slippery.
<b>7.0</b>	<b>Handling and Storage</b>	
7.1	Handling	For use only by dental professionals. Follow good hygiene practices. Do not smoke, eat or drink while using. Cap powder and liquid immediately after use. Avoid cross-contamination of parts.
7.2	Storage	Keep containers tightly closed. Store each part in original container at cool room temperature (< 25°C) and in a dry, well-ventilated area. Avoid direct, strong light, sources of ignition and extremes of temperature (>27°C/80°F, <5°C/40°F). Provided that the material has been stored properly, shelf life for unopened powder is five years from date of manufacture; shelf life for unopened liquid is three years from date of manufacture.
7.3	Specific uses	Professional dental material
<b>8.0</b>	<b>Exposure Controls / Personal Protection</b>	

Trade Name: **PULPDENT ROOT CANAL SEALER POWDER AND LIQUID**

<b>8.1</b>	Exposure limit values	Zinc oxide: PEL: 5 mg/m <sup>3</sup> . TLV: 10 mg/m <sup>3</sup> . Eugenol: Not established	
<b>8.2</b>	Exposure controls		
<b>8.2.1</b>	Occupational exposure controls	No special equipment required under normal conditions of use of this product in the quantity provided.	
<b>8.2.1.1</b>	Respiratory protection	None required. Good general ventilation is sufficient to control any nuisance dust or airborne vapors during normal conditions of use.	
<b>8.2.1.2</b>	Hand protection	Usual surgical gloves worn by dental staff will limit contact with material.	
<b>8.2.1.3</b>	Eye protection	Usual safety glasses worn by dental staff.	
<b>8.2.1.4</b>	Skin protection	Good personal hygiene and safety practices and wearing a lab coat should protect dental staff from unnecessary exposure to material.	
<b>8.2.1.5</b>	Other controls	Emergency eye wash fountain should be available. Wash hands after use.	
<b>8.2.2</b>	Environmental exposure controls	Powder is inert. Liquid should not be discharged into environment.	
<b>9.0</b>	<b>Physical and Chemical Properties</b>		
<b>9.1</b>	Appearance / Color	<u>Powder</u> Fine powder	<u>Liquid</u> Oily liquid
<b>9.1.1</b>	Color	White	Colorless to pale yellow
<b>9.1.2</b>	Odor	None	Cloves
<b>9.2</b>	Important health, safety and environmental information		
<b>9.2.1</b>	pH	Not applicable	7.0
<b>9.2.2</b>	Boiling point	Not applicable	253°C
<b>9.2.3</b>	Flash point	Not applicable	112°C
<b>9.2.4</b>	Flammability (solid, gas)	Not determined	Not applicable
<b>9.2.5</b>	Explosive properties	Not applicable	Not applicable
<b>9.2.6</b>	Oxidizing properties	Not determined	Not an oxygen donor
<b>9.2.7</b>	Vapor pressure	< 1 mm Hg / 133 Pa	< 0.1 mm Hg
<b>9.2.8</b>	Specific gravity	5.650	1.064
<b>9.2.9</b>	Solubility in water	Nil	Slight
<b>9.2.10</b>	Partition coefficient	Not determined	Not determined
<b>9.2.11</b>	Viscosity	Not determined	Not determined
<b>9.2.12</b>	Vapor density	Not determined	Not determined
<b>9.2.13</b>	Evaporation rate	Not determined	Not determined

Trade Name: **PULPDENT ROOT CANAL SEALER POWDER AND LIQUID**

<b>10.0</b>	<b>Stability and reactivity</b>	
10.1	Conditions to avoid	Temperature > 38°C, light, air, cross-contamination.
10.2	Materials to avoid	Powder: Strong oxidizing agents. Liquid: Ferric chloride, potassium permanganate.
10.3	Hazardous decomposition products	Carbon monoxide and carbon dioxide.
10.4	Further information	Eugenol is not pyrophoric, does not react with water, is not an oxygen donor and is shock stable.
<b>11.0</b>	<b>Toxicological information</b>	
11.1	Acute toxicity	Not toxic. Minimal health hazard in the quantities present in this product and under normal conditions of use.
11.2	Irritation and corrosiveness	Both powder and liquid may be irritating to eyes, respiratory system or skin on contact or with prolonged exposure.
11.3	Sensitization	Liquid may be sensitizing. Prolonged or frequent inhalation or skin contact may cause allergic reactions in some susceptible individuals.
11.4	Sub-acute, sub-chronic and prolonged toxicity	Prolonged exposure to large amounts of zinc oxide may cause dermatitis unless good personal hygiene is practiced. Prolonged exposure to powder or liquid may cause eye and respiratory irritation.
11.5	Carcinogenicity, Mutagenicity, Reproductive Toxicity	None known
11.6	Empirical data	Not available
11.7	Clinical experience	Zinc oxide/eugenol cements, like Root Canal Sealer, have been used successfully in dental procedures for more than 70 years. They are considered to be safe and effective treatment.
<b>12.0</b>	<b>Ecological Information</b>	
12.1	Ecotoxicity	To the best of our knowledge, Root Canal Sealer powder is inert. Root Canal Sealer Liquid should not be discharged into the environment. No other information is available.
<b>13.0</b>	<b>Disposal Considerations</b>	
13.1	Regulations	Follow all local and national government regulations in disposing material or contaminated packaging.
<b>14.0</b>	<b>Transport Information</b>	
14.1	Restrictions	None. Not regulated.
<b>15.0</b>	<b>Regulatory Information</b>	
15.1	EU	Class IIa medical device under MDD 93/42/EEC.
15.2	US FDA	Class II medical device.

Trade Name: **PULPDENT ROOT CANAL SEALER POWDER AND LIQUID**

15.3	Health Canada	Class III medical device
<b>16.0</b>	<b>Other information</b>	
<b>16.1</b>	List of relevant R phrases	R36/37/38, Irritating to eyes, respiratory system and skin. R42/43, May be sensitizing by inhalation or skin contact.
<b>16.2</b>	Hazard Statements	H319: Eye irritation. 2. May cause eye irritation. H335: STOT SE. 3. May cause respiratory irritation. H315: Skin irritation. 2. May cause skin irritation. H317: Sensitization. 1. May cause an allergic skin reaction. H334: Respiratory sensitization. 1. May cause allergy or asthma symptoms.
<b>16.3</b>	Precautionary Statements	P261: Avoid breathing vapor. P280: Wear protective gloves and eye protection P342+P311: If experiencing respiratory symptoms, call a poison center or doctor/physician. P305+P351: If in eyes, rinse cautiously with water for several minutes. P337+P313: If eye irritation persists, get medical advice/attention. P302+P352: If on skin, wash with plenty of soap and water. P333+P313: If irritation or rash occurs, get medical advice/attention.
<b>16.4</b>	Restrictions on use	Root Canal Sealer is to be sold to and used by dental professionals only.
<b>16.5</b>	Further information	The information presented herein is believed to be factual as it has been derived from the works of persons believed to be qualified experts. However, nothing contained in this information is to be taken as a warranty or representation for which Pulpdent Corporation bears legal responsibility. The user should review any recommendations in the specific context of the intended use to determine whether they are appropriate.
<b>16.5</b>	Sources of key data	National Institute for Occupational Safety (NIOSH) US Occupational Safety and Health Administration (OSHA) Eur-Lex European Union Law: Regulation (EC) No. 1272/2008 (CLP) and Regulation (EC) No. 1907/2006 (REACH). Guidance on the compilation of safety data sheets. Version 1.1; December 2011. European Chemicals Agency
<b>16.6</b>	Information which has been added, deleted or revised.	This Safety Data Sheet has been revised to meet the GHS SDS format and the requirements of Regulation (EC) No. 1272/2008 (CLP) and Regulation (EC) No. 1907/2006 (REACH). Specifically Sections 2.1, 2.2, 3.2, 16.2, 16.3 have been modified.